

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION**

Civil Action No. 5:20-cv-536

BECTON, DICKINSON AND
COMPANY,

Plaintiff,

vs.

BIOMEDOMICS, INC.

Defendant.

COMPLAINT

Plaintiff Becton, Dickinson and Company (“BD”) hereby alleges against the Defendant BioMedomics, Inc. (“BioMedomics” or “Defendant”) the following:

PARTIES

1. BD is a corporation existing by virtue of the laws of the State of New Jersey that has its principal place of business at One Becton Drive, Franklin Lakes, New Jersey 07417. Thus, BD is a citizen of New Jersey.
2. BioMedomics is a corporation existing by virtue of the laws of the State of North Carolina that has its principal place of business at 1100 Perimeter Park Drive, Morrisville, North Carolina 27560. Thus, BioMedomics is a citizen of North Carolina.
3. BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics and the delivery of care.
4. BioMedomics holds itself out as being in the business of manufacturing and selling clinical diagnostics products to address various global healthcare needs.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a)(2) in that there is complete diversity of citizenship between the parties and the amount in controversy exceeds \$75,000.00, as noted below.

6. Venue is proper within this district based on 28 U.S.C. § 1391 in that Defendant resides in this district.

FACTS

7. On or about March 26, 2020, BD and BioMedomics entered into a Term Sheet for Exclusive Distribution Agreement (the “Term Sheet”).

8. Pursuant to the Term Sheet, BioMedomics was to manufacture and sell multiple units of COVID-19 IgM/IgG assay (the “Product”) to BD.

9. The Product is a serology test which is represented by BioMedomics to detect the presence of antibodies in the blood when the body is responding to an infection.

10. In entering into the Term Sheet, BioMedomics understood and agreed that the Product was to be used in the United States in connection to the presently occurring Coronavirus pandemic.

11. Under the Term Sheet, BioMedomics was to be solely responsible for manufacturing the Product to meet all applicable laws and regulations, including the regulations of the Federal Drug Administration (“FDA”).

12. The Term Sheet was explicitly binding with respect to any purchase orders delivered by BD to BioMedomics for the Product.

13. Under the Term Sheet, BD was required to prepay for one hundred percent of the Product purchased pursuant to BD’s initial purchase order and second purchase order for the Product.

14. BD and BioMedomics performed according to the terms of the Term Sheet as follows:

- A. On March 29, 2020, BD submitted an initial purchase order for 1,000,000 units of the Product along with prepayment in the amount of \$4,000,000.00.
 - B. On April 9, 2020, BioMedomics began fulfilling the initial purchase order by delivering 50,000 units of the Product to BD.
 - C. On April 15, 2020, BD submitted a second purchase order for 500,000 units of the Product along with prepayment in the amount of \$2,125,000.00.
 - D. On April 23, 2020, BD received another 50,000 units of the Product from BioMedomics, pursuant to the purchase orders.
15. BD agreed to receive the Product from BioMedomics with the understanding that the Product would be permitted by applicable laws and regulations such that the Product could be sold in the United States.
16. Under the Term Sheet, if the Product were not permitted to be sold in the United States due to applicable laws and regulations, BioMedomics was to provide a refund to BD for the full amount paid for the Product.
17. On May 4, 2020, the FDA issued a notice that would require the Product to qualify for an Emergency Use Authorization (“EUA”) prior to being sold on the open market.
18. An EUA is issued by the FDA during a public health emergency to allow for the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.
19. Thereafter, on May 27, 2020, BioMedomics submitted an EUA application to the FDA for the Product.

20. On June 11, 2020, BioMedomics issued a medical device recall for the Product pursuant to the FDA's May 4, 2020 notice, requesting that all remaining units of the product be returned or destroyed.

21. Following BioMedomics' recall of the Product, BD returned or destroyed the remaining portions of the 100,000 units of the Product it had already received.

22. On July 28, 2020, the FDA issued a notice to BioMedomics stating that the Product did not satisfy the requirements for EUA.

23. BD actively cooperated with BioMedomics in its efforts to secure the EUA.

24. However, as of the date of this filing, BioMedomics has not obtained the required EUA for the sale and distribution of the Product from the FDA. Consequently, the Product is non-conforming and unsalable.

25. As a result of BioMedomics' inability to ensure that the Product continued to be permitted to be sold pursuant to applicable laws and regulations in the United States, BD sent a notice on August 14, 2020 stating that it did not intend to continue its relationship with BioMedomics and demanded a full repayment of its prepayment for the Product, which repayment was expressly required under the Term Sheet.

26. By letter dated September 4, 2020, BioMedomics refused to refund BD's prepayment for the Product and has thereafter continued such refusal.

FIRST CAUSE OF ACTION
(BREACH OF CONTRACT)

27. BD realleges the allegations set forth in the above paragraphs and the same are incorporated by reference as if fully set forth herein.

28. All conditions precedent to the bringing of this claim have been satisfied, have occurred, or have been waived.

29. According to the explicit terms of the Term Sheet, “If the Product is recalled, or no longer permitted (by applicable law or regulation) or able to be sold in the Territory in which it is contemplated to be sold, BioMedomics will provide refund to BD for the full amount paid by BD for such Product.”

30. Despite demand, BioMedomics has failed and refused to pay BD all amounts due under the Term Sheet leaving a balance due of \$6,125,000.00.

31. BioMedomics’ failure to maintain the required FDA authorization described hereinabove in order to render the Product conforming and salable, which lead to the recall of the Product, and BioMedomics’ subsequent failure to refund timely to BD all sums due and owing to BD under the Term Sheet constitutes a breach of contract.

32. Due to BioMedomics’ breach, BioMedomics has proximately caused damages to BD, and BD is entitled to recover in this action from BioMedomics the sum of \$6,125,000.00, in addition to lost profits and pre- and post-judgment interest and costs as provided by law.

SECOND CAUSE OF ACTION
(UNJUST ENRICHMENT)

33. BD realleges the allegations set forth in the above paragraphs and the same are incorporated by reference as if fully set forth herein.

34. Alternatively, as a proximate result of the acts and omissions of BioMedomics as described hereinabove, BioMedomics has been and will be unjustly enriched if it is permitted to retain the benefit conferred upon it of the \$6,125,000.00 prepayment tendered by BD for the purchase of the Product.

35. Consequently, in the alternative, BD is entitled to a judgment requiring disgorgement of the prepayment sum from BioMedomics and/or an equitable lien and/or a constructive trust on same.

WHEREFORE, Plaintiff Becton, Dickinson and Company respectfully prays the Court as follows:

1. That the Court award judgment in favor of Plaintiff and against Defendant in the amount of \$6,125,000.00, in addition to lost profits and pre- and post-judgment interest, or alternatively, for a judgment requiring disgorgement of such moneys and/or an equitable lien and/or a constructive trust on same;
2. That the costs of this action, including reasonable attorney's fees, be taxed against the Defendant to the extent permitted by applicable law;
3. For a trial by jury on all issues; and
4. For such other and further relief as the Court deems just and equitable.

This the 8th day of October 2020.

NELSON MULLINS RILEY & SCARBOROUGH LLP

/s/ Mark A. Stafford

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